6 510(K) SUMMARY

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Trade Name of Device: Trima Accel System

Common Name: Automated Blood Component Collection System

Classification Name: Class II
In accordance with 21 CFR 864.9245(b), the classification for this device is Class II with special controls.

Predicate Devices: Trima Accel System, Version 6.4 (BK140158)

Device Description:
The Trima Accel system is comprised of three subsystems: the apheresis machine (or equipment), embedded software, and a single-use disposable blood tubing set. The Trima Accel® MobilePro Package is intended for use with the Trima Accel System. The package contains four replacement wheels, two replacement bumpers, and an automatic brake. The modifications are described below.

Table 1: Modifications included in the Trima Accel MobilePro Package

	Modification	Reason for Change	Impact of Change
1	Addition of a rear default-engaged (automatic) hand braking system. Minor modifications were made to caster assembly and bumper to accommodate rear braking system.	Increased control during transport of the machine in a mobiles environment.	No functional impact to the procedures performed on the Trima Accel System. No change to safety or effectiveness of the device.
2	Labeling – Instructions for Use	New instructions for use document for the rear hand braking system.	

Intended Use/Indications for Use:
The Trima Accel System is an automated blood cell separator intended for use in collecting blood components for later transfusion into patients.

Depending on the disposable tubing set used, the Trima Accel system has been cleared to collect:

- Double ACD-A/AS-3 Red Blood Cells (leukocytes reduced or not leukoreduced)

Or the following products alone or in combination:

- ACD-A/AS-3 Red Blood Cells
- ACD-A/AS-3 Red Blood Cells, Leukocytes Reduced utilizing an integrated filter (TLR gravity drain filter or Auto RBC filter)
- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (Isoplate) (single or double units)
- Platelets Pheresis, Platelet Additive Solution (Isoplate) (triple units) Note: For triple platelet collections (platelet yield greater than 9.0 x 10e11), the product can be labeled as leukocytes reduced if the residual WBC content is tested and determined to meet the U.S. leukoreduction specifications. Products that do not meet the U.S. leukoreduction specifications must be discarded.
- Plasma
  - Fresh Frozen Plasma and Fresh Frozen Plasma, Leukocytes Reduced
    - Must be prepared and placed in a freezer at -18 °C or colder within 8 hours of Phlebotomy.
  - Plasma Frozen Within 24 Hours After Phlebotomy (PF24) and Plasma Frozen Within 24 Hours After Phlebotomy, Leukocytes Reduced
    - Must be stored at 1°C to 6°C within 8 hours of Phlebotomy and placed in a freezer at -18 °C or colder within 24 hours of Phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
  - Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24) and Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy, Leukocytes Reduced
    - Can be stored at room temperature for up to 24 hours after Phlebotomy. Product must be placed in a freezer at -18 °C or colder within 24 hours of Phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
  - Source Plasma

Platelet Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards. Platelets Pheresis, Leukocyte Reduced, Platelet Additive Solution (Isoplate) (single or double units) may be further processed (e.g., irradiated, divided). Platelets Pheresis, Platelet Additive Solution (Isoplate) (single or double units) may **not** be manufactured from products that do not meet leukocyte reduction product standards.

The Trima Blood Component Sampling Assembly, which is either integrated into the disposable tubing sets or as an accessory for sterile connection, is intended to allow aseptic removal of a

sample from the platelet bag for subsequent bacterial or other applicable testing. The Sampling Assembly does not have contact with blood fluids that are reinfused to a donor or patient.

- Adequate studies have not been performed to evaluate the effect of gamma irradiation or freezing on the quality of ACD-A/AS-3 red blood cells products (RBCs) collected with gravity drain leukoreduction process (TLR filter) on the Trima Accel system.

- Studies have not been performed to support gamma irradiation or freezing of ACD-A/AS-3 RBCs collected with an integrated in-line RBC leukoreduction filter(s) (Auto RBC filter) on the Trima Accel system.

Rx Only.

Acceptance Criteria and Parameters:

RBCs collected on the Trima Accel system using the Auto RBC feature as either a single unit or double units, with continuous RBC leukoreduction, and stored in ACD-A/AS-3 for 42 days met the following acceptance criteria required by the FDA-CBER:

Primary Outcomes
95% probability and a one-sided 95% confidence limit:

- the number of contaminating leukocytes per unit is less than 5 million
- the recovery of RBCs after leukoreduction is greater than 85%
- RBC hemolysis is less than 1.0%

The mean recovery at 24 hours for each unit is ≥75% with standard deviation ≤9%; and the one sided 95% lower confidence limit for the population proportion of successes is >70% (successes = individual units recovery ≥75%).

Secondary Outcomes
The results of biochemical tests for ATP and Potassium levels at the end of storage failed to show with 95% confidence that greater than 95% of the products will be within 20% of the Control product. Results of ATP levels for Test for a single RBC collection were not significantly different from Control by a paired t test analysis (p-value = 0.80). Results of ATP levels for Test for double RBC collections were significantly better than Control by a paired t test analysis (two-sided p-value = 0.014). Results of Potassium levels for Test for a single RBC collection were significantly better than Control by a paired t test analysis (p-value = 0.0354). Results of Potassium levels for Test for double RBC collections were not significantly different from Control by a paired t test analysis (two-sided p-value = 0.566).

The pH results support the conclusion with 95% confidence that more than 95% of the products will have a difference between Test and Control of less than 0.5 pH units at the end of RBC shelf life. The clinical significance of the secondary outcomes is unknown.

The Trima Accel system includes a modified platelet post-count algorithm. U.S. customers should not set the minimum post-count below 100,000/ μL.

The following table summarizes the plasma product parameters from a paired study comparing PF24RT24 (apheresis plasma held at room temperature and frozen 24 hours post-collection) and FFP (apheresis plasma held at room temperature and frozen 8 hours post-collection).

Summary of PF24RT24 (Test) and FFP (Control) Plasma Product Parameters (N=52)							
Coagulation Assay	**Mean (SD)**		**Median**		**(Minimum, Maximum)**		**Mean Difference (Test- Control) (95% Confidence Interval)**
	Control	**Test**	**Control**	**Test**	**Control**	**Test**	
PT (seconds)	12.0 (0.6)	12.1 (0.6)	11.8	12.0	10.7, 13.7	10.9, 13.8	0.1 (0.1, 0.2)
aPTT (seconds)	37.9 (3.9)	38.5 (3.8)	37.7	38.5	31.1, 47.7	31.6, 48.6	0.6 (0.2, 0.9)
Factor V (IU/dL)	100.4 (17.6)	99.5 (16.5)	102.5	100.5	52, 138	52, 136	-0.9 (-2.0, 0.2)
Factor VIII (IU/dL)	79.8 (25.0)	72.6 (24.1)	74.0	67.5	37, 163	36, 157	-7.2 (-9.3, -5.1)
Factor XI (IU/dL)	73.5 (11.4)	73.8 (11.0)	71.5	71	53, 109	52, 103	0.3 (-0.4, 1.0)
vWF (IU/dL)	91.7 (29.1)	89.4 (28.2)	90.5	87	44, 145	41, 145	-2.3 (-4.2, -0.4)
Protein C (IU/dL)	97.9 (14.0)	94.3 (13.4)	99	98	65, 123	62, 126	-3.7 (-5.5, -1.9)
Protein S (IU/dL)	93.3 (20.0)	83.0 (19.2)	91.5	80.5	53, 161	48, 145	-10.3 (-12.4,-8.2)
AT III (IU/dL)	103.1 (7.7)	102.8 (7.8)	103	102.5	85, 120	85, 116	-0.3 (-1.4, 0.9)
Factor VIIa	2.6 (1.2)	2.7 (1.3)	2.4	2.3	0.6, 6.1	1.2, 6.4	0.1 (-0.3, 0.4)
FPA	9.2 (12.2)	9.9 (11.1)	4.0	4.9	0.6, 57.5	0.4, 44.9	0.6 (-3.4, 4.7)

Technological Comparison:

The modified Trima Accel System with the MobilePro Package does not change the system's fundamental scientific technology or principle of operation; that is, the separation of blood into its components using centrifugation.

Substantial Equivalence:

The modified Trima Accel System with the MobilePro Package is substantially equivalent to its predicate and is summarized below:

Attribute		***Comparison***
1	**Intended Use (System)**	No change to the intended use as a result of the modifications
2	**Technology, Engineering, Performance**	None of the changes described above impact the current indications for use and did not require clinical data or otherwise impact safety and efficacy of the Trima Accel System.